This is an official CDC Health Advisory

Distributed via Health Alert Network August 29, 2005, 11:30am

Nosocomial Burkholderia cepacia pneumonia associated with contaminated alcohol-free mouthwash

Background Information

The Centers for Disease Control and Prevention (CDC) has been notified by several states of clusters of pneumonia and other infections caused by Burkholderia cepacia. These cases had exposure to alcohol-free mouthwash manufactured by Carrington Labs (Irving, TX) for Medline Industries (Mundelein, IL). Cultures performed by a hospital laboratory where the first cases were detected indicate that multiple lots of Medline alcohol-free mouthwash are intrinsically contaminated with B. cepacia. In August 2005, the Texas Department of State Health Services was notified of a cluster of nosocomial pneumonia involving three patients hospitalized at a Texas health-care facility.

All three patients were intubated and in the intensive care unit for their underlying illnesses when they developed signs of pneumonia and respiratory cultures grew B. cepacia. All three patients had received oral care using 4 oz. bottles of Medline alcohol-free mouthwash prior to illness onset. One patient has recovered and has been discharged. The second and third remain hospitalized, one with a poor prognosis. Molecular typing is pending. An additional two clusters (2 cases and 5 cases), both associated with prior use of Medline alcohol-free mouthwash, are currently being investigated in two Florida health-care facilities.

CDC is working with state health departments and the Food and Drug Administration to determine the magnitude of this outbreak. Carrington Labs analysis of in-house retain samples has confirmed contamination in multiple lots of the product in both 4 oz. and 2 oz. bottles leading to a recall of all alcohol-free mouthwash manufactured by Carrington Labs for Medline.

Product-specific Information

The suspect product bears a 7 or 8 digit lot number on the bottom of the bottle; suspect lot numbers include numbers 0503*** through 0508*** and 0503**** through 0508*** (asterisks represent any digit). The product is available in 2 oz. bottles as well as 4 oz. bottles and was distributed only to hospitals and long term care facilities.

The product <u>is not distributed for direct retail sale to the consumer</u>. However, the 2 oz. bottles are packaged with other items, such as toothbrushes, toothpaste, etc. by Medline into a 'personal hygiene hospital admission kit' so some mouthwash may be in the possession of the consumer within a residential setting.

Medline alcohol-free mouthwash with the above lot numbers should not be used.

DHEC Contact Information for Reportable Diseases and Reporting Requirements

Individuals who are aware of cases of B. cepacia colonization or infection occurring during or shortly after exposure to these products should contact their health department and CDC at 1-800-893-0485.

Reporting of cases or probable cases is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2004 List of Reportable Conditions available at: http://www.scdhec.gov/health/disease/docs/reportable_conditions.pdf

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

Public Health Offices

Mail or call reports to the Epidemiology/Disease Report Office in the appropriate county listed below.

Region 1

(Anderson, Oconee)

220 McGee Road Anderson, SC 29625 Phone: (864) 231-1966 Fax: (864) 260-5623

Nights / Weekends: 1-(866)-298-4442

(Abbeville, Edgefield, Greenwood, Laurens, McCormick, Saluda)

PO Box 3227 1736 S. Main Street Greenwood, SC 29646 Phone: 1-888-218-5475 Fax: (864) 942-3690

Nights / Weekends: 1-800-420-1915

Region 2

(Cherokee, Spartanburg, Union)

PO Box 4217 151 E. Wood Street Spartanburg, SC 29305-4217 Phone: (864) 596-2227 ext. 210 Fax: (864) 596-3443

Nights / Weekends: (864) 809-3825

(Greenville, Pickens)

PO Box 2507 200 University Ridge Greenville, SC 29602-2507 Phone: (864) 282-4139 Fax: (864) 282-4373 Nights / Weekends: (864) 460-5355 or Region 3

(Chester, Lancaster, York)

PO Box 817 1833 Pageland Highway Lancaster, SC 29721 Phone: (803) 286-9948 Fax: (803) 286-5418

Nights / Weekends: 1-(866)-867-3886 or

1-(888)-739-0748

(Fairfield, Lexington, Newberry, Richland)

2000 Hampton Street Columbia, SC 29204 Phone: (803) 576-2749 Fax: (803) 576-2993

Nights / Weekends: (803) 304-4252

Region 4

(Clarendon, Kershaw, Lee, Sumter)

PO Box 1628 105 North Magnolia Street Sumter, SC 29150 Phone: (803) 773-5511 Fax: (803) 773-6366

Nights / Weekends: 1-(877)-831-4647

(Chesterfield, Darlington, Dillon, Florence, Marlboro, Marion)

145 E. Cheves Street Florence, SC 29506 Phone: (843) 661-4830 Fax: (843) 661-4859

Nights / Weekends: (843) 660-8145

Region 5

(Aiken, Allendale, Barnwell)

1680 Richland Avenue, W. Suite 40 Aiken, SC 29801 Phone: (803) 642-1618 Fax: (803) 643-8386

Nights / Weekends: (803) 827-8668 or

1-800-614-1519

Region 5 (cont.)

(Bamberg, Calhoun, Orangeburg)

PO Box 1126 1550 Carolina Avenue Orangeburg, SC 29116 Phone: (803) 533-7199 Fax: (803) 536-9118

Nights / Weekends: (803) 954-8513

Region 6

(Georgetown, Horry, Williamsburg)

2830 Oak Street Conway, SC 29526-4560 Phone: (843) 365-3126 Fax: (843) 365-3153

Nights / Weekends: (843) 381-6710

Region 7

(Berkeley, Charleston, Dorchester)

4050 Bridge View Drive, Suite 600 N. Charleston, SC 29405 Phone: 843-746-3806 Fax: (843) 746-3851

Nights / Weekends: (843) 219-8470

Region 8

(Beaufort, Colleton, Hampton, Jasper)

1235 Lady's Street Port Royal, SC 29935 Phone: (843) 525-7603 Fax: (843) 525-7621

Nights / Weekends: 1-800-614-4698

Bureau of Disease Control

Acute Disease Epidemiology Division 1751 Calhoun Street Box 101106 Columbia, SC Phone: (803) 898-0861 Fax: (803) 898-0897

Nights / Weekends: 1-888-847-0902

Categories of Health Alert messages:

1-800-993-1186

Health Alert conveys the highest level of importance; warrants immediate action or attention.

Health Advisory provides important information for a specific incident or situation; may not require immediate action. **Health Update** provides updated information regarding an incident or situation; unlikely to require immediate action.